510(k) Summary **Item 6**

Date prepared: December 16, 2002

Submitter's Information

FEB 1 2 2003

Company Name	D. E. Hokanson, Inc
Establishment Registration Number	3019130
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City, State, Zip, Country	Bellevue, WA 98040, USA
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Contact Person	D. Eugene Hokanson
Title	President
E-mail	gene@deh-inc.com

Trade Name, Common Name, Classification

Trade Name:	Hokanson Blood Flow Measuring System
Common Name	Venous Occlusion Flow Measuring System
Classification Name	Strain Gauge Plethysmograph System
Device Class	Class II
Product Code	AI6

Identification of Predicate Device(s)

The AI6 combines elements and functions of the following devices:

Device	Manufacturer	510(k)
Strain Gauge Plethysmograph	Hokanson	K982707
Rapid Cuff Inflator	Hokanson	K905367
ECG Trigger	Hokanson	K973426
Deltran 1 Pressure Transducer	Utah Medical	K841788/C
NIVP3 Computer Program	Hokanson	K932852

Description of the Device

The AI6 Blood Flow Measuring system measures blood flow in one or two limbs or digits simultaneously using the principles of venous occlusion plethysmography. This involves inflating a blood pressure cuff on the proximal part of the limb to a pressure that exceeds the venous pressure in the limb, but which is less than the arterial pressure. The cuff inflation is done quickly so as to obtain a distinct starting point for the measurement. When the cuff is inflated the limb begins to swell due to the blood flowing into the limb since the normal venous outflow is stopped by the cuff. The resulting change in the volume of the limb is measured by the plethysmographs and the rate of change is equal to the blood flow at the moment of venous occlusion. The AI6 is controlled by a computer program that causes the cuff inflators to inflate, records the plethysmographic volume measurements and calculates the rate of change of volume. By combining the instruments and controlling them with one computer it is possible to make measurements in quick succession and more easily analyze the results.

510(k) Summary Continued

Intended Use

The intended use of the AI6 is the measurement of arterial blood flow by means of venous occlusion plethysmography. The AI6 replaces the predicate instruments which are used primarily in research studies. Applications include studies that relate to protocols that influence limb blood flow through exercise, reactive hyperemia, or the influence of drugs.

Non-clinical tests showing equivalence.

The accuracy of venous occlusion plethysmographic measurements depends primarily on two things. One is the calibration and accuracy of the strain gauge plethysmograph and the other is the speed and pressure control of the venous occlusion cuffs.

The accuracy of the strain gauge plethysmographs is the same as that of the predicate device by using the same technology and by employing the same strain gauges. The results of mechanical calibration tests show the AI6 to be equal to the EC6 predicate device.

The accuracy of the pressure regulators is identical to that of the predicate device since the same pressure regulator is used. Although the exact pressure is not very critical in venous occlusion plethysmography, the pressure setting is actually improved in the new device since the pressure is controlled by the computer in a closed-loop system whereas the predicate device is set manually. The requirement is that the pressure in the venous occlusion cuff should be above venous pressure and below arterial pressure, i.e. somewhere between 15 and 100 mmHg. Usually a venous occlusion pressure of 50 to 60 mmHg is chosen in practice. The pressure accuracy of the AI6 is within plus or minus 1 mmHg.

The speed of inflation is controlled by the size of the valves and tubing that connect to the cuff. The tubing used in the AI6 is identical to that used in the E20 predicate device. The valves have a slightly higher Cv than those in the predicate device. The inflation rate measured by inflating a test object is equal to that of the predicate device. Our largest blood pressure cuff can be inflated by the AI6 from 0 to 50 mmHg in less than 300 mSec. In order to show a distinct starting point for a measurement it is desirable to inflate the venous occlusion cuff in less than one heart beat.

The conclusions to be drawn from these tests are that the AI6 is equal to the predicate devices in accuracy and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

D.E. Hokanson, Inc.
c/o Mr. D. Eugene Hokanson
President
12840 NE 21st Place
Bellevue, WA 98005

Re: K023707
Trade Name: Hokanson Blood Flow Measuring System
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM
Dated: January 27, 2003
Received: February 4, 2003

Dear Mr. Hokanson:

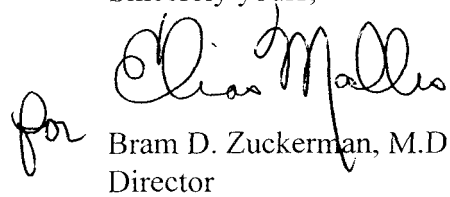
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement (modified) **Item 1**

The intended use of the AI6 is the measurement of blood flow by means of venous occlusion plethysmography. This is the same usage as one of the uses of our EC6 Plethysmograph and it has not changed.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023707

Prescription Use X
(Per 21 CFR 801.109)